REMARKS

In accordance with the foregoing, claims 33-36 has been added. Claims 1-36 are pending and under consideration.

In items 2 and 3 of the Office Action, the Examiner raises provisional obviousness type double patenting rejections based on co-pending U.S. Application No. 09/826,418. Item 1 mentions that a terminal disclaimer can be used to overcome the rejections. The Examiner is requested to hold the requirement for a terminal disclaimer in abeyance until at least one of the applications is indicated as otherwise being in condition for allowance.

In item 6, the Examiner rejects claims 1, 4-7, 15 and 18-21 under 35 U.S.C. § 103(a) as being obvious over the inventor's prior U.S. Patent No. 5,749,203. ("the '203 patent"). Applicant previously argued that the '203 patent does not suggest using a pretreatment area having a heat source to heat the medical article. The Examiner addresses this argument beginning in the paragraph bridging pages 8 and 9 of the Office Action. The Examiner appears to believe the '203 patent teaches preheating can or should be used with a form-fill-and-seal device.

The '203 patent describes preheating only in connection with a prior art system, which is significantly different from that claimed. The '203 patent describes a sterilization process known as the Anderson Steri-Jet™ process. The Anderson process is described in the Background of the Invention section of the '203 patent. Referring to column 2, lines 37-42, the Anderson process involves placing articles into preformed bags. This is significantly different from a process that employs an article loading station where a medical article is loaded into a housing in a first web; an alignment device to align a second web with the first web; and a sterilization-sealing station where the first web and the second web, with the medical article loaded into the housing, are sterilized, and then, the first and second webs are sealed together. In the Anderson process, there are no webs. Instead, a preformed bag is sealed on three sides. Accordingly, an alignment device is not necessary. According to the claims, a housing is formed in a first web. In the Anderson process, a housing is formed by forming the bag. Perhaps the Examiner believes that the Anderson bag is analogous to the claimed housing in the first web. However, the claims also recite that a second web is aligned with the first web. In the Anderson process, there is no second web aligned with the housing. If the Examiner is confused regarding the differences between the Anderson system and the claimed device and method, the Examiner is requested to telephone the undersigned. The two systems are very different.

Although the '203 patent mentions preconditioning, there is no suggestion to use a pretreatment area having a heat source when there are first and second webs that are aligned sterilized and then sealed. The '203 patent describes that the length of time is a drawback of the prior art processes, including the Anderson process. The '203 patent therefore teaches away from preheating when using a first web into which a housing is formed, a second web that is aligned with the first web, which first and second webs are sealed after sterilization.

The simple fact that the '203 patent mentions both preheating and using first and second webs does not mean that the '203 patent suggest using preheating with the first and second webs. By analogy, assume a document described problems associated with coal fired steam engines in connection with railroad trains. If this same document described gasoline engines being used in automobiles to address the problems with coal fired steam engines in railroad trains, then this document would not suggest using a coal fired steam engine in an automobile.

It is respectfully submitted that the courts have held that the Examiner may not suggest modifying references using the present invention as a template absent a suggestion of the desirability of the modification in the prior art. *In re Fitch*, 23 U.S.P.Q.2d 1780, Fed Cir. 1992. Something in the prior art as a whole must suggest the desirability, and thus, the obviousness, of making the combination. *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F. 2d 1490, 1 U.S.P.Q. 2d 1337 (Fed. Cir. 1986). When a rejection depends on a combination of prior art references, there must be some teaching, suggestion or motivation to combine the references. *In re Geiger*, 815 F.2d 686, 688 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987).

The genius of invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of patent claims, the law requires some "teaching, suggestion or reason" to combine cited references. Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997). When the art in question is relatively simple, as is the case here, the opportunity to judge by hindsight is particularly tempting. Consequently, the tests of whether to combine references need to be applied rigorously. See In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999), limited on other grounds by In re Gartside, 203 F.3d 1305, 53 USPQ2d 1769 (2000) (guarding against falling victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher).

There is no suggestion to use a pretreatment area having a heat source as claimed in

claim 1. Further, there is no suggestion for preheating a medical article in a pretreatment area, as claimed in claim 15. At least for these reasons, independent claims 1 and 15, and the claims dependent thereon, pantentably distinguish over the '203 patent.

Claims 2, 3, 8-14, 16, 17 and 22-32 are rejected under 35 U.S.C. § 103(a) as being obvious over the '203 patent in view of a Multivac Packaging Machines reference. With regard to independent claim 8, this claim recites a sterilization sealing station comprising gas injection pins to inject gas into the housing. Independent claim 22 recites injecting gas into the housing between the first and second webs, through gas injection pins. The Examiner admits that the '203 patent does not disclose injecting gas using pins. The Multivac Packaging Machines reference is cited for this purpose. The Examiner asserts that it would have been obvious to use the Multivac pins in the '203 patent "in order to establish a uniformity of gas distribution." The Examiner is referring to an advantage stated in the Multivac reference on page 1, column 1. This advantage is "Since pins are located on both sides of [the] die, uniformity of gas distribution is easy to obtain." The advantage describes the difference between using pins on one side of a die versus using pins on both sides of a die. Perhaps this advantage renders obvious having pins on both sides of a die if they were previously present on only one side of a die. However, this advantage in no way renders obvious using gas injection pins in the '203 patent (where they were not present before).

As the title indicates, the Multivac gas injection pins are used for gas flushing. Gas flushing is when one gas is replaced with another gas. For example, if a bag contained food and air, the pins could be used to inject carbon dioxide into the bag until a substantial portion of the air were displaced. In this manner, the color and taste of the food may be preserved.

On the other hand, gas displacement is not necessary in the '203 patent. Column 9, lines 32-37 of the '203 patent describes that the chamber is evacuated. Oxygen is removed from the chamber without a gas flushing process. Column 10, lines 1-46 of the '203 patent describes how the evacuation is performed. Referring to Fig. 4B, after a lid 418 and a seal die 424 are secured together, three chambers are formed. These chambers are represented with the letters A, B and C in Fig. 4B. The chambers A and C are evacuated respectively through ports 420 and 428. Chamber B is evacuated through port 448 in nozzle 446. With the evacuation, there is substantially no need for gas displacement, flushing, as proposed by the Multivac reference.

Page 3, column 1 of the Multivac reference describes typical applications as packaging

for red meats, sausage, pork, poultry, fish, cheese, bakery products and fruits and vegetables. On the other hand, the '203 patent is directed to a very different application, namely sterilization of medical articles.

It appears that the Examiner is using prohibitive hindsight in making the rejection. As mentioned above, the '203 patent discloses a nozzle 446 and a port 448. Is the Examiner proposing that it would have been obvious to use the Multivac pins in addition to the nozzle 446? Alternatively, does the Examiner propose to use the pins instead of the nozzle 446. If the Examiner proposes to eliminate the nozzle 446, where is the motivation for doing this? The present invention, not the prior art, suggests using pins instead of a nozzle. There is no motivation to make the changes suggested by the Examiner. Accordingly, the obviousness rejection should be withdrawn.

With regard to new claims 33-36, new independent claim 33 recites that gas is injected between the first and second webs without a ported nozzle position between the first and second webs. Antecedent basis for this limitation can be found for example at page 4, lines 1-3, page 4, line 21 through page 5, line 3 and in the drawings of the application, as filed. In view of the above remarks, it should be readily apparent that the prior art does not suggest eliminating the ported nozzle from the device disclosed in the '203 patent. Dependent claims 34-36 contain important limitations, the patentability for which is discussed above.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance, except for possible provisional obviousness type double patenting rejections. An early action indicating allowable subject matter is respectfully requested.

If there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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